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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte DETLEF GRAWE, SABINE GLIESING, HAGEN GERECKE, PETER HOESEL, UWE MUELLER, THOMAS MICHEL, ROBERT EILERS, UWE KNABE, BERND ERHART, MICHAEL MOSEBACH, DAVID VOIGTLAENDER, ULF TILSTAM, JURGEN JACKE, KLAUS BAHL, ULF BOHLMANN, DIETER WEHMEIER, and MICHAEL SANDER

Appeal 2015-004471
Application 13/690,736
Technology Center 1600

Before DONALD E. ADAMS, ERIC B. GRIMES, and DAVID COTTA, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL[1]

This appeal under 35 U.S.C. § 134(a) involves claims 1–16, 18–20, and 22–26 (Br. 3). Examiner entered a rejection under 35 U.S.C. § 102(b). We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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[1] Appellants identify the real party in interest as "BAYER PHARMA AG" (Br. 1).

STATEMENT OF THE CASE

Appellants' claim 1 is reproduced below:

1. Amorphous, physically pure asoprisnil microparticles obtainable by a method comprising reacting

17β-Hydroxyestra-4,9-dien-3-one (hydroxyestradienone)

↓

3,3-Dimethoxyestra-5(10),9(11)-diene-17-one (nordienedione ketal)

↓

3,3,17β-Trimethoxy-17α-methoxymethylestra-5(10),9(11)-diene (trimethoxydiene)

↓

4-[17β-Methoxy-17α(methoxymethyl)-3-oxoestra-4,9-dien-11β-yl]-benzaldehyde (dienone aldehyde)

↓

11β-[4-(Hydroxyiminomethyl)-phenyl-17β-methoxy-17α-methoxymethyl-estra4,9-dien-3-one (asoprisnil)

by a process comprising:

a) synthesizing nordienedione ketal from hydroxyestradienone either

- by oxidation of 17β-hydroxyestra-4,9-dien-3-one (hydroxyestradienone) to estra-4,9-diene-3,17-dione (nordienedione) and subsequent selective ketalization to 3,3 dimethoxyestra-5(10),9(11)-diene-17-one (nordienedione ketal) or
- ketalizing hydroxyestradienone to 17β-hydroxy-3,3-dimethoxyestra-5(10),9(11)-diene (hydroxy ketal) and subsequently oxidizing to nordienedione ketal,

b) synthesizing trimethoxydiene from nordienedione ketal in three steps via the stages 3,3-dimethoxyestra-5(10),9(11)-diene-17β-spiro-1',2'-oxirane (nordienespirane) and 3,3-dimethoxy-17α-methoxymethylestra-5(10),9(11)-dien-17β-ol (nordiene ether), not isolating nordienespirane and nordiene ether,

c) synthesizing 3,3,17β-trimethoxy-11β-[4-(dimethoxy-methyl)phenyl]-17α-methoxymethylestr-9-en-5α-ol (dimethoxy acetal) from trimethoxydiene via 17α(methoxymethyl)-3,3,17β-trimethoxy-5α,10α-epoxyestr-9(11)-ene (enepoxide) in a Cu(I)-catalyzed Grignard reaction with bromobenzaldehyde dimethyl acetal,

d) synthesizing the dienone aldehyde by reaction with acids,

e) synthesizing asoprisnil from dienone aldehyde with a hydroxyamine hydrochloride solution,

f) purifying by chromatography,

g) drying.

(Br. 5–6.)

Claims 1–16, 18–20, and 22–27 stand rejected under 35 U.S.C. § 102(b) as anticipated by Grawe.[2]

ISSUE

Does the preponderance of evidence on this record support Examiner's finding that Grawe teaches Appellants' claimed invention?

ANALYSIS

Examiner finds that Grawe anticipates Appellants' claimed invention (Ans. 2–5). We adopt Examiner's findings concerning the scope and content of the prior art (Ans. 2–5). In this regard, Examiner finds that "[t]he compound and compositions taught by [Grawe] are encompassed by [Appellants'] claim[]" 1 and "the patentability of a product does not depend on it[s] method of production" (Ans. 3 and 4). Examiner further finds that Grawe teaches "that under [the] ICH-stability test, the amorphous structure

[2] Grawe et al., WO 01/90137 A2, published Nov. 29, 2001, Examiner relies on the "English equivalent" of this reference, Grawe et al., US 2004/0006241 A1, published Jan. 8, 2004 (*see* Ans. 2).

[of Grawe's product] does not show any signs of a recrystallization and/or chemical decomposition after 12 months" (Ans. 5, citing Grawe ¶ 27).

Appellants contend that Grawe discloses "the preparation of asoprisnl [sic] on a laboratory scale" not "on a pilot or manufacturing scale" (Br. 3). We are not persuaded. As Examiner explains, Appellants' "claims[,] as recited[,] are drawn to 'amorphous, physically pure asoprisnil microparticles" and do not require the production of any particular amount of the compound (Ans. 4–5).

For the reasons provided by Examiner, we are not persuaded by Appellants' contentions regarding the ICH-stability of the claimed product (*see* Ans. 5; *cf.* Br. 3–4).

CONCLUSION OF LAW

The preponderance of evidence on this record supports Examiner's finding that Grawe teaches Appellants' claimed invention. The rejection of claim 1 under 35 U.S.C. § 102(b) as being anticipated by Grawe is affirmed. Claims 2–16, 18–20, and 22–27 are not separately argued and fall with claim 1.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED